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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,793	10/01/2001	Benedito Da Silva	TIN-0017	5160

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CANTOR COLBURN, LLP  
55 GRIFFIN ROAD SOUTH  
BLOOMFIELD, CT 06002

EXAMINER
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COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/868,793

Applicant(s)

Da Silva

Examiner

Rebecca Cook

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1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11-24 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 2-15 have been renumbered as claims 11-24.

✓ Furthermore, original claims 1-10 on pages 5-6 were not canceled. However, it appears from the applicant's remarks in the amendment of 10/1/01 that the intent is to replace them with the claims submitted in said amendment. Therefore, for the purposes of compact prosecution only the claims submitted in the preliminary amendment have been examined. Applicant is requested to cancel original claims 1-10 on pages 5-6.

✓ A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter. Furthermore, the use of "Compound I" and Compound II" is confusing. They should be replaced with the full names of the compounds each time they appear in the specification. Additionally, it is not clear what is meant by the words "solvato," "massification," "doorway," and "lisar."

✓ The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

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Claims 11-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of alpha-hydroxypropionic acid to treat sinusitis, does not reasonably provide enablement for any and all respiratory diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It is not seen that alpha-hydroxypropionic acid would be useful to treat asthma or black-lung disease. Amending the claim 11 to recite "sinusitis" will overcome this rejection.

Claims 11-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

No recipient is recited in claim 11. Furthermore, the wording of the claim renders the method unclear. Amending it to recite "A method of treating sinusitis in a human or animal in need thereof comprising administering a composition comprising alpha-hydroxypropionic acid...." will overcome this rejection.

In claim 15 the word "includes" renders it unclear as to what other disease are intended to be claimed.

In claims 15 and 16 it is not clear what "highairway" disease means. In claim 19 it is not clear what is meant by "clearing agent of nasal cavities." It is not seen that these are defined in the specification.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 6317323A (abstract).

'323 discloses that alpha-hydroxypropionic acid is useful in the treatment of respiratory disease. The instant claims differ over the reference in recited amounts and specific solvents. However, in the absence of a showing of unexpected results commensurate in scope with the claims in Declaration form, once a method of using a compound is known it would be obvious to one of ordinary skill in the art to determine the optimum amount and solvent.

Applicant is requested to submit an IDS.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Friday from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

June 13, 2002

  
REBECCA COOK  
PRIMARY EXAMINER  
GROUP 1200/614